CALLS TO ACTION

With the objective to incentivise continuous optimisation on existing treatments, there is an urge to change how decision-makers & healthcare community stakeholders assess and evaluate price and market access of value added medicines. Therefore, we propose the following calls to action:

Supportive payer mechanisms

1. Ensure price and market access potentials are proportional to the value of value added medicines
2. Consider relevant value dimensions that demonstrate the benefits of value added medicines in the different purchasing/procurement mechanisms
3. Introduce flexibility to assess and reassess price with pragmatic* evidence that demonstrates the benefits of VAMs
4. Agree upfront and implement the pragmatic evidence requirements between the various healthcare stakeholders:
    - Patient preference studies, patient reported outcomes (PROs), healthcare professionals' (HCP) preference studies, patient advocacy group opinions, etc.
    - Other pragmatic* value demonstration of the benefits of VAMs, such as descriptive studies that demonstrate/quantify VAM benefits (e.g. RWE studies such as event rates in a cohort, user handling studies, etc.) or analytical methods in the context of value of information (e.g. historical control RWE studies, parallel control RWE studies, etc.)

**Pragmatic evidence – flexible and efficient evidence that is tailored to demonstrate the different levels of benefits of value added medicines*

5. Implement a mechanism to recognise VAM value and ensure differentiation with standard generics, that takes into consideration the voice of all relevant healthcare stakeholders which can include patients, physicians, nurses and pharmacists, throughout the decision-making process
    - Similarly to Belgium, markets should implement mechanisms through which VAMs can be differentiated from standard of care, potentially achieving price premiums to standard of care depending on the additional benefit.

Supportive regulatory framework

6. Implement a specific definition for value added medicines to avoid classification with standard generics
7. Allow regulatory incentives for value added medicines that stimulate R&D investment without creating lifelong unjustified protections of off-patented medicines
8. Create an opportunity for binding early dialogues between regulatory and price and reimbursement authorities